Filed by Caladrius Biosciences, Inc.
Pursuant to Rule 425 under the Securities Act of 1933
and deemed filed pursuant to Rule 14a-12
of the Securities Exchange Act of 1934, amended
Subject Company: Caladrius Biosciences, Inc.
Commission File No.: 001-33650

Caladrius Biosciences Announces Merger Partner, Cend Therapeutics, has Treated First Patient in Phase 2b Trial of CEND-1 in Collaboration with Australasian Gastro-Intestinal Cancer Trials Group

BASKING RIDGE, N.J. (June 9, 2022) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease, announces that its merger partner in the creation of Lisata Therapeutics ("Lisata"), Cend Therapeutics, Inc. ("Cend") today indicated that the first patient has been treated in the Phase 2b study of CEND-1 in combination with gemcitabine and nab-paclitaxel for the treatment of first-line, metastatic pancreatic ductal adenocarcinoma. The ASCEND trial is a 125-patient, double-blind, randomized, placebo-controlled clinical trial being conducted at up to 40 sites in Australia and New Zealand led by the Australasian Gastro-Intestinal Cancer Trials Group ("AGITG") in collaboration with the NHMRC Clinical Trial Centre at the University of Sydney. Cend will provide study drug and regulatory support. The continued development of CEND-1 is the subject of a collaboration agreement with and investment in Cend by Caladrius. It is expected that Cend-1 will become the centerpiece of the combined development pipelines of Cend and Caladrius under the Lisata banner.

"This is an exciting and important step in the advancement of CEND-1 and for patients with pancreatic cancer, which has an extremely high mortality rate and affects hundreds of thousands of patients globally each year. We know how hard the team at Cend has worked to get this study initiated," stated Kristen K. Buck, M.D., Executive Vice President of R&D and Chief Medical Officer of Caladrius. "We hope to report a number of further additional clinical advancements around Cend's pipeline in the coming months as we progress under our joint development agreement prior to the closing of the proposed merger."

## **About CEND-1**

CEND-1 is an investigational drug that modifies the tumor microenvironment. It is targeted to tumor vasculature by its affinity for *alpha*-v integrins that are selectively expressed in tumor, but not healthy tissue vasculature. CEND-1 is a cyclic peptide that, once bound to these integrins, is cleaved by proteases expressed in tumors to release a peptide fragment, called a CendR fragment, which binds to a second receptor, called neuropilin-1, to activate a novel uptake pathway that allows anticancer drugs to more selectively penetrate solid tumors. The ability of CEND-1 to modify the tumor microenvironment to enhance delivery and efficacy of co-administered drugs has been demonstrated in models of a range of solid tumors.

## **About Caladrius Biosciences**

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of innovative therapies designed to treat or reverse disease. We currently are developing first-in-class autologous cell therapy products based on the finely tuned mechanisms for self-repair that exist in the human body. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company's current product candidates include: XOWNA® (CLBS16), the subject of both a recently completed positive Phase 2a study and an ongoing Phase 2b study (<a href="www.freedom-trial.com">www.freedom-trial.com</a>) in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS12 (HONEDRA® in Japan), recipient of a SAKIGAKE designation in Japan and eligible for early conditional approval for the treatment of critical limb ischemia ("CLI")

and Buerger's disease based on the results of an ongoing clinical trial; and CLBS201, designed to assess the safety and efficacy of CD34+ cell therapy as a treatment for diabetic kidney disease ("DKD"). For more information on the Company, please visit <a href="www.caladrius.com">www.caladrius.com</a>.

The Company recently announced that it has signed a definitive merger agreement with Cend Therapeutics, Inc. (www.cendrx.com). The merger is expected to close in the third quarter of 2022.

## **About Cend Therapeutics**

Cend is a clinical-stage biotech company focused on a novel approach to enable more effective treatments for solid tumor cancers. The CendR Platform<sup>TM</sup> provides a tumor-targeted tissue penetration capability to specifically enhance drug delivery to tumors. Cend is also applying its technology to alter immunosuppression selectively within the tumor microenvironment to enable a patient's immune system and immunotherapies to fight cancer with greater effectiveness. For more information on Cend, please visit www.cendrx.com

# Forward-Looking Statements

This communication contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forwardlooking statements. In addition, when or if used in this communication, the words "may," "could," "should," "anticipate," "estimate," "expect," "intend," "plan," "predict", "see" and similar expressions and their variants, as they relate to Caladrius, Cend or the management of either company, before or after the aforementioned merger, may identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements relating to the timing and completion of the proposed merger; Caladrius's continued listing on the Nasdaq Capital Market until closing of the proposed merger; the combined company's listing on the Nasdaq Capital Market after closing of the proposed merger; expectations regarding the capitalization, resources and ownership structure of the combined company; the approach Cend is taking to discover and develop novel therapeutics; the adequacy of the combined company's capital to support its future operations and its ability to successfully initiate and complete clinical trials; the difficulty in predicting the time and cost of development of Cend's product candidates; the nature, strategy and focus of the combined company; the executive and board structure of the combined company; and expectations regarding voting by Caladrius's and Cend's stockholders. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the risk that the conditions to the closing of the transaction are not satisfied, including the failure to timely or at all obtain stockholder approval for the transaction; uncertainties as to the timing of the consummation of the transaction and the ability of each of Caladrius and Cend to consummate the transaction; risks related to Caladrius's ability to correctly estimate its operating expenses and its expenses associated with the transaction; the ability of Caladrius or Cend to protect their respective intellectual property rights; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Caladrius's Annual Report on Form 10-K filed with the SEC on March 22, 2022. Caladrius can give no assurance that the conditions to the transaction will be satisfied. Except as required by applicable law, Caladrius undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

# No Offer or Solicitation

This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained,

the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

## Important Additional Information Will be Filed with the SEC

In connection with the proposed transaction between Caladrius and Cend, Caladrius intends to file relevant materials with the SEC, including a registration statement that will contain a proxy statement and prospectus. CALADRIUS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT CALADRIUS, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and shareholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement, prospectus and other documents filed by Caladrius with the SEC by contacting Investor Relations by mail at Attn: Investor Relations, Caladrius Biosciences, Inc., 800 Westchester Avenue, Suite N341, Rye Brook, NY 10573. Investors and stockholders are urged to read the proxy statement, prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

# Participants in the Solicitation

Caladrius and Cend, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction. Information about Caladrius's directors and executive officers is included in Caladrius's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 22, 2022 and amended on April 21, 2022. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement relating to the transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated below.

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